IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Takuji MAEJIMA et al.

Group Art Unit: 1624

Appl. No.: 10/598,303

Examiner: Brenda COLEMAN

Filed: August 24, 2006

Confirmation No.: 2558

For: FASUDIL-CONTAINING PREPARATION AND METHOD OF IMPROVING STABILITY THEREOF

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and §§ 1.97-1.98, and further to the Information Disclosure Statements filed January 9, 2007 and March 4, 2009, Applicants hereby direct the Examiner's attention to the following information.

Applicants note that the documents submitted herewith are in the Japanese language, and accordingly, verified partial or full translations of each is provided herewith. Applicants note that the following documents, numbered 1, 2, and 3, are identified for ease of reference on the documents, in the translations, and in the verification as "M1," "M2," and "M3," respectively.

1) Asahi Kasei Pharma Products Information from 2003 for the Eril injection preparation (October 2003 revision; 6th edition); accompanied by an English language translation thereof; Applicants note that the information indicates the product had a pH of 5.7-6.3

2) Asahi Kasei Pharma Products Information from 2003, showing photos of Asahi Kasei Pharma Products; Applicants note that the photos show the product packaged in a brown ampoule

3) "Interview Form" for Eril, a document in which Eril is described in detail; document is prepared by pharmaceutical manufacturer upon request of Japan Hospital Pharmaceutical Association and is considered a comprehensive manual for such pharmaceutical; accompanied by an English language translation of pages 3-7; Applicants note that the document indicates that the drug is provided in a brown ampoule (see section IV-10) and has a pH of 5.7-6.3 (see section IV-1(2))

Applicants note that the M3 document (#3 above) includes attachments relating to "Change-in-pH test" and "Change caused by mixing with other agents," and Applicants note that attachments such as this are commonly included in Interview Forms relating to injectable agents. "Change-in-pH test" indicates the change over the pH range illustrated (and for this drug, shows no change). "Change caused by mixing with other agents" indicates the change in appearance and other attributes when the drug is mixed with other agents as listed.

With respect to the M3 document (#3 above), Applicants recognized while preparing the verified translation that there were some errors in the original document. In the second part of the table under "Change-in-pH test," the original (Japanese language) version refers to "(B) 1/10N HCl," whereas it should refer to "(B) 1/10N NaOH." The translation corrects this error.

Applicants also note that the values for the pH and transmission rates for Pansporin and Broact (under the Antibiotics (613) section) in the table attachment for "Change caused by mixing with other agents" appear to be transposed. That is, the pH values for Pansporin in the

columns for "Immediately After," "30 minutes later," "2 hours later," and "6 hours later" are 66.4, 60.5, 45.8, and 25.6, respectively, and the transmission rates are 6.42, 6.42, 6.53, and 6.61. These values appear to have been transposed, as the pH values obviously must be between 0 and 14. Two entries down in the same table, under Broact, the same transposition appears to have been made. Applicants note that the translation does not correct these transpositions, and Applicants bring this information to the attention of the Office so that the record is clear.

Applicants note that the documents listed above are duly listed on an attached Form PTO-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office. If the Examiner needs additional copies of any of the documents, the Examiner is requested to contact the undersigned.

Citation of any document herein shall not be construed as: (1) an admission that the document is necessarily prior art with respect to the instant invention; (2) a representation that a search has been made; or (3) an admission that the information cited herein is, or is considered to be, material to patentability in any way, including that as defined in §1.56(b).

Applicants note that this Supplemental IDS is being filed after a first Office Action on the merits, and accordingly, the required fee for consideration of the information is included herewith. Applicants hereby authorize the charging of any required fees necessary for consideration of this IDS and any information cited herein to Deposit Account No. 19-0089.

If the Examiner has any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
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